

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 8, 2010 has been entered.

Amendment Entry

2. The amendment filed March 31, 2010 has been entered. Claims 38 and 54 have been amended. Claims 1-37, 39-40, 43, 45-53, 56-60 and 62-68 are cancelled. Claims 38, 41-42, 44, 54-55 and 61 are under consideration in this office action.

Oath/Declaration

3. The declaration of Neil A. Williams, under 37 CFR 1.132 filed March 31, 2010 is acknowledged.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

Art Unit: 1645

by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sheridan Snedden on October 26, 2010.

The application has been amended as follows:

Claim 38. (Currently Amended) A method of generating a cytotoxic CD8+ T-lymphocyte cell-mediated protective immune response against a herpes virus infection, in a mammal in need thereof, comprising co-administering to the mammal a therapeutically effective amount of Escherichia coli heat labile enterotoxin B subunit (EtxB), and an antigen, wherein the EtxB is free from whole toxin and is not linked to the antigen, wherein the antigen is a virus antigen from the herpes virus family, thereby generating the cytotoxic CD8+ T-lymphocyte cell-mediated protective immune response against a herpes virus infection.

Claim 54. (Currently Amended) A method of generating a cytotoxic CD8+ T-lymphocyte cell-mediated protective immune response against an infection, in a mammal in need thereof, comprising administering to the mammal between 50 and 100 ug of Escherichia coli heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin, and an antigen, wherein the EtxB and antigen are not linked to form a single active agent.

Withdrawal of Objections and Rejections

5. The following objections and rejections have been withdrawn in view of applicants' amendments, arguments and declaration under 37 CFR 1.132:

- a) The objection of claims 58-59 under 37 CFR 1.75(c);
- b) The rejection of claims 38, 41-42, 44 and 58 under 35 U.S.C. 112, second paragraph; and
- c) The rejection of claims 38, 41-42, 44, 54-55, 58-59 and 61 under 35 U.S.C. 103(a) as being unpatentable over Richards et al., (1997. Vaccine. Vol. 15(10): 1065-1069) in view of Williams et al., (WO 97/02045 published January 23, 1997).

Allowable Subject Matter

6. Claims 38, 41-42, 44, 54-55 and 61 are allowed.

7. The following is an examiner's statement of reasons for allowance: The prior art does not teach or suggest a method of generating a cytotoxic CD8+ T-lymphocyte cell-mediated protective immune response against a herpes virus infection, as instantly claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor Patricia Duffy, can be reached on 571-272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645